

REMARKS

The March 27, 2007, Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the March 27, 2007, Official Action. Therefore, the initial due date for response is June 27, 2007. This response is being filed within the initial 3 month response period.

Applicants note that the Examiner has deemed the restriction requirement proper and has made it final. Accordingly, claims 7-19 are withdrawn from consideration and claims 1-6 have been examined on the merits. Further, the Examiner notes that process of making claims will be rejoined upon the allowance of a product claims. Applicants also respectfully request that Group IV, claims 13 and 16-18, be rejoined in accordance with MPEP §821.04(b) as methods of using the product.

Turning to the substantive aspects of the March 27, 2007, Official Action, at page 3, the Examiner has rejected claims 1-6 for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph for containing subject matter which was not described in such a way as to convey to the skilled artisan that Applicants were in possession of the invention at the time the application was filed.

At page 4 of the Official Action, the Examiner has rejected claims 1-3 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent 5,968,775 to Houghton et al.

The Examiner has also rejected claim 1 under 35 U.S.C. §102(b) as allegedly anticipated by Seipp et al. (J. Gen. Virol.

(1997) 78:2467-2476) and by Kato et al. (Jpn. J. Cancer Res. (1996) 87:787-792).

Lastly, the Examiner rejected claims 1, 4, and 5 under 35 U.S.C. §102(b) as allegedly anticipated by Sasagawa et al. (Biochem. Biophys. Res. Comm. (2000) 272:647-680) and by Wu et al. (PNAS (1994) 91:674-678).

The foregoing rejections constitute all of the grounds set forth in the March 27, 2007, Official Action for refusing the present application. In view of the foregoing amendments and the following remarks, these grounds of rejection cannot be reasonably maintained, and therefore, are respectfully traversed.

In accordance with the instant amendment, Applicants have cancelled claims 2, 3, 10, 12 and 19; amended claims 1, 9, and 11; and added new claims 20-31. Support for the amendment to claim 1 can be found throughout the specification including, for example, in Example I. Withdrawn claims 9 and 11 have been amended to depend from product claims 1 and 20 to expedite rejoinder. Additionally, claims 9 and 11 have been amended to recite the features previously recited in claims 10 and 12, respectively. Support for new claim 20 can be found, for example, in original claim 1 and Example I (see pages 36-45). Original claims 2 and 3 provide support for new claims 21 and 22. Claims 23-26, which are supported by original claims 13 and 16-18, are drawn to the withdrawn invention of Group IV. However, as stated hereinabove, withdrawn method of use will be rejoined upon the allowance of a product claim. The addition of new claim 20 necessitated the addition of claims 23-26. Support for new claims 27-31 can be found, for example, throughout Example I (see pages 36-45). No new matter has been introduced into this application by reason of any of the amendments presented herewith.

**CLAIMS 1-6, AS AMENDED, SATISFY THE WRITTEN DESCRIPTION
REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH**

It is the Examiner's position that claims 1-6 fail to satisfy the written description requirement under 35 U.S.C. § 112, first paragraph; the Examiner states that this is a new matter rejection. Specifically, the Examiner asserts that the original claims did not recite the negative limitations added by amendment to claims 1 and 4 (i.e., "non-monkey, non-chimpanzee, non-mosquito" cell lines), and further notes that Applicant's specific exclusion of particular organisms is not implicit in the specification.

Applicants respectfully disagree with the Examiner's position. However, in the sole interest of expediting prosecution of the instant application, Applicants have eliminated the negative limitation from the claims, thereby overcoming the instant rejection. Withdrawal of the rejection is respectfully requested.

CLAIMS 1-3, AS AMENDED, ARE NOT ANTICIPATED BY HOUGHTON ET AL.

The Examiner has rejected claims 1-3 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent 5,968,775 to Houghton et al. It is the Examiner's position that Houghton et al. teach the generation and use of human cell lines including B- and T-cell lines infected with HCV, and specifically teaches HeLa cells when listing candidate cell lines naturally producing suspected HCV receptors and coreceptors.

Applicants respectfully disagree with the Examiner's position and submit that Houghton et al. fail to disclose a cell line identical to that of Applicants. It is a well-settled premise in patent law that in order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference

must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

At the outset, Applicants have amended claim 1 to recite a mouse cell line. Houghton et al. fail to teach mouse cell lines. Indeed, the Examiner did not include claims 4-6, drawn to mouse hepatic cell lines, in the instant rejection. It is evident from the above that the instant rejection of claim 1 is untenable as Houghton et al. fail to teach each and every element of claim 1. Withdrawal of the rejection is respectfully requested.

Applicants have added new claim 20 which recites that the cell line is a human non-hepatic cell line and that the cell line comprises the RNA from a second cell line which comprises an HCV genome. The instant specification demonstrates in Example I that a human non-hepatic cell line that replicates HCV can be generated, for example, by transfecting human non-hepatic cells with the total RNA from human hepatic cells that replicate HCV. Houghton et al. fail to teach or suggest such cell lines. Indeed, while Houghton et al. describe the transfection of cells with an HCV RNA obtained from *in vitro* transcription (see, e.g., column 17), Houghton et al. fail to teach the transfection of cells with the total RNA from an HCV permissive cell line, as instantly claimed.

Further, Applicants note that the HeLa cells contemplated by Houghton et al. are transfected with a vector providing for expression of a receptor (column 14, lines 5-7). No such modification of the HeLa cell line is required by the instant invention.

In light of the foregoing, it is clear that the present claims have novelty over the disclosure of Houghton et al., and Applicants respectfully submit that the rejection of claims 1-3 is inappropriate and request its withdrawal.

**CLAIM 1, AS AMENDED, IS NOT ANTICIPATED BY SEIPP ET AL. OR KATO
ET AL.**

Claim 1 stands rejected under 35 U.S.C. §102(b) as allegedly anticipated by Seipp et al. and by Kato et al. The Examiner contends that Seipp et al. disclose the use of human and non-human cell lines, including porcine non-hepatoma cell lines, for supporting HCV replication. Kato et al. allegedly teach the use of a human non-neoplastic cell line of hepatic origin for supporting HCV replication.

As stated hereinabove, Applicants have amended the claims to recite mouse cells and human non-hepatic cells. In contrast, Seipp et al. describe porcine cell lines and human hepatoma cell lines and Kato et al. describe a "non-neoplastic human hepatocyte line." Inasmuch as Seipp et al. and Kato et al. do not teach each and every element of the claimed invention, it is clear that the instant 35 U.S.C. §102(b) rejections are untenable. Accordingly, withdrawal of these rejections is respectfully requested.

**CLAIMS 1, 4, AND 5, AS AMENDED, ARE NOT ANTICIPATED BY SASAGAWA
ET AL. AND WU ET AL.**

Claims 1, 4, and 5 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Sasagawa et al. and by Wu et al. The Examiner contends that Sasagawa et al. disclose Hepal-6 cells and Wu et al. teach AML12 cells. However, the Examiner acknowledges that these references do not teach or suggest that these cells have an HCV replicative capacity.

As stated hereinabove, Applicants have amended the instant claims to recite that the cell lines comprise a HCV genome or HCV subgenome. Inasmuch as Sasagawa et al. and Wu et al. fail to teach or suggest cells replicating HCV, Applicants respectfully submit that the instant rejections are untenable.

Withdrawal of the rejections is respectfully requested.

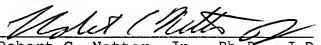
CONCLUSION

In view of the amendments presented herewith and the foregoing remarks, it is respectfully urged that the rejections set forth in the March 27, 2007, Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,
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